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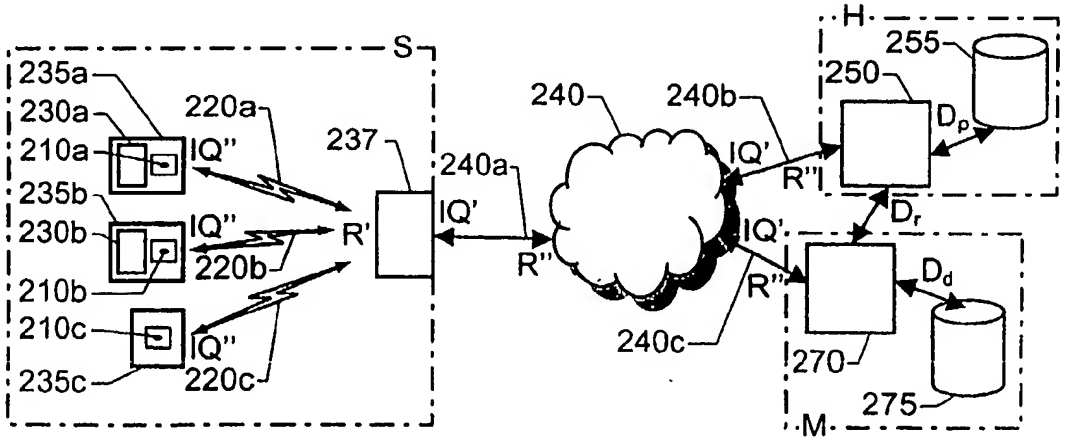

(57) Abstract: The invention relates to organization of not yet implanted implantable medical devices (210a-c) that are associated with telemetry means (C) for wireless exchange of data (IQ'', R') with a remote external unit (250; 270). According to the invention, at least one inquiry signal (IQ'') is transmitted from a local administration unit (237) to at least one telemetry means (C) via a wireless interface (220a-c). At least one return signal (R') is sent back from the telemetry means (C) to the local administration unit (237) over the same interface (220a-c) in response to the at least one inquiry signal (IQ''). This communication allows the remote external unit (250; 270) to extract information pertaining, for instance, the process of physically locating a particular device (210a-c), which in turn may be useful when performing administrative procedures, such as recall operations, billing and stocktaking.

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Management of Implantable Devices

THE BACKGROUND OF THE INVENTION AND PRIOR ART

The present invention relates generally to implantable medical devices that are associated with telemetry means for wireless data exchange with external units. More particularly the invention relates to a method of organizing not yet implanted implantable medical devices according to claim 1, a computer program according to claim 8, a computer readable medium according to claim 9, a system according to claim 10 and a local administration unit according to claim 18.

In recent years the processing and data storage capacity of implantable medical devices (IMD), such as pacemakers, has increased dramatically. Following this advancement, the means of interacting with these kinds of devices has likewise been developed. Today, a broad spectrum of different systems are therefore known for supervising and re-programming implanted medical devices over various kinds of communication networks.

Figure 1 illustrates a typical structure for such a system. A medical device 110 having a telemetry means is here presumed to be implanted into a patient 115. The device 110 is able to exchange data D_R with a repeater unit 130 via a wireless channel 120, which is set up between the telemetry means in the repeater unit 130 over the network 140. The repeater unit 130, in turn, has a network interface 140a towards a communications network 140. An external unit 150, e.g. a remote programmer, also has a network interface 140b towards the network 140 and may thus communicate with the repeater unit 130. This, in combination with the wireless channel 120, accomplishes a chain of communication between the external unit 150 and the device 110, which preferably is bi-directional. Classically, measurement data is sent from the device 110 to

the external unit 150, while control commands, parameter settings and/or re-programming code is transmitted in the reverse direction. In most cases, the external unit 150 is linked to a data store 160 including at least a patient database. The device's 110 characteristics and mode of operation can thereby be adjusted, for example based on historical measurement data from the device 110, which has been loaded into the data store 160 earlier.

U.S. patent No. 6,249,705 discloses a distributed network system for use with IMDs, which enables a multitude of programmers to communicate with a specific IMD. A network server allows each programmer to exploit a far greater amount of processing power than a stand-alone programmer. Moreover, a database linked to the network server provides easy information access to the physicians as well as a basis for software updates of the IMDs.

U.S. patent No. 6,292,698 shows a world wide patient location and data telemetry system for IMDs through which the function of the devices may be selectively monitored. Telemetry data may here be transmitted via a satellite network, a wired telephone network or a cellular telephone network.

The published U.S. patent application No. 20010031997 describes a data communication system, which permits collaboration between distributed clinicians regarding distributed or remote IMDs. By means of the system, an implanted medical device may be polled by an interface device external to the host patient and data may be transmitted to the interface device through wireless communication. This data may then be sent to a central computer for storage and further distribution.

The international patent application WO01/82210 describes a component architecture for medical devices system networks, which are intended to administer implanted medical devices over at least one network, such as the Internet. The proposed system

enables a central computing resource to exchange data with a particular medical device which is implanted into the body of a patient. Naturally, the existence of the device in question inside the body is here presumed to be known on beforehand. Moreover, before initiating the data exchange, the patient must position himself/herself within a communication range of a network interface being adapted to communicate with the implanted device.

Thus, the prior art includes many examples of solutions for remote supervising and re-programming of implanted medical devices. However, there is no corresponding solution for administrating IMDs. Therefore, all administrative procedures in respect of devices in this category must be effected on a manual basis, which in many cases can be both resource and time consuming. For instance, if a recall of devices becomes necessary, this typically affects only not yet implanted devices. Still, locating each relevant device could prove to be a very complex task, particularly since a given batch of devices may be distributed to a large number of retailers and hospitals around the globe.

Other problems are billing and stocktaking, i.e. to maintain an updated inventory of devices currently in stock, either at the manufacturer or at a retailer.

Furthermore, in emergency situations it may be life critical to quickly find a suitable IMD for a specific patient. A large local stock (at e.g. a hospital), which includes a wide variety of products here poses an additional problem.

SUMMARY OF THE INVENTION

It is therefore an object of the present invention to alleviate the problems above and thus provide an improved solution for organizing not yet implanted IMDs.

According to one aspect of the invention these objects are achieved by a method of organizing not yet implanted IMDs, where each IMD is presumed to be associated with a respective telemetry means for wireless exchange of data with a remote external unit. The method involves communicating at least one inquiry signal and at least one return signal over a wireless interface between at least one telemetry means and a local administration unit. Specifically, these signals establish the existence of at least one implantable medical device. The method also involves matching registered device identities against information contained in an inquiry signal, and determining a course of action to be taken in respect of at least one implantable medical device based on the result of said matching.

An important advantage attained by this procedure is that the remote external unit thereby is able to automatically administrate not yet implanted IMDs. For example, a total number of devices of a particular model and version in stock may effortlessly be acquired. Moreover, in case of a recall situation, the inquiry signal may include a recall message and the at least one return signal may include identifications specifying the locations of any not yet implanted devices that should be recalled. Thereby, an automated recall procedure is supported.

According to a preferred embodiment of this aspect of the invention, the method further involves generating a primary inquiry signal in the remote external unit and broadcasting a secondary inquiry signal over a wireless interface. The secondary inquiry signal is based on the primary inquiry signal. Moreover, the method involves receiving, via the wireless interface, the secondary inquiry signal in at least one telemetry means and generating, in response to the secondary inquiry signal, a respective primary return signal in at least each of the at least one telemetry means, which are associated with a device that fulfills a requirement specified in the secondary inquiry signal. Additionally, the method involves transmitting, via

the wireless interface, the at least one primary return signal from the at least one telemetry means and forwarding, to the remote external unit, a secondary return signal being based on the at least one primary return signal.

This procedure is advantageous because it makes it possible to adapt the signal formats to the relevant transmission media. Furthermore, an aggregated secondary return signal may be generated, which is based on two or more primary return signals.

According to a preferred embodiment of this aspect of the invention, the method involves retrieving device data that pertains to at least one IMD from a first central data store, and generating the primary inquiry signal on basis of this device data. Thereby, automated recall and stocktaking procedures are further supported.

According to a preferred embodiment of this aspect of the invention, the method involves entering patient data that indicates at least one patient specific parameter with respect to a potential user of an IMD, and generating the primary inquiry signal on basis of the patient data, possibly in combination with the device data. Thereby, procedures for finding a unit most suitable for a specific patient are supported, which is advantageous in many situations. Preferably, the patient data is retrieved from a second central data store.

According to another aspect of the invention these objects are achieved by a computer program directly loadable into the internal memory of a digital computer, comprising software for controlling the method described above when said program is run on a computer.

According to yet another aspect of the invention these objects are achieved by a computer readable medium, having a program recorded thereon, where the program is to make a computer perform the method described above.

According to still another aspect of the invention these objects are achieved by a system for organizing not yet implanted IMDs, where each IMD is associated with a respective telemetry means for wireless exchange of data with a remote external unit. The system includes a local administration unit, which is adapted to communicate at least one inquiry signal and at least one return signal with at least one telemetry means over a wireless interface, establish the existence of at least one implantable medical device, and match registered device identities against information contained in an inquiry. The system also includes at least one remote external unit which has a network connection to the local administration unit and is adapted to determine a course of action to be taken in respect of at least one implantable medical device based on the result of a matching performed by the local administration unit.

Such system is advantageous, since it allows the remote external unit to automatically administrate the not yet implanted IMDs, for instance, during stocktaking, billing or when a recalling devices.

According to a preferred embodiment of this aspect of the invention, the system includes a first central data store, which contains device data pertaining to at least one IMD. Moreover, the system contains a first remote external unit adapted to retrieve device data from the first central data store and on basis thereof generate a primary inquiry signal, and receive and process a secondary return signal. The local administration unit within the system is adapted to receive the primary inquiry signal and on basis thereof generate a secondary inquiry signal. The local administration unit is also adapted to broadcast the secondary inquiry signal over the wireless interface and receive at least one primary return signal over this interface. Additionally, the system includes at least one telemetry means adapted to receive the secondary inquiry signal via the wireless interface, and in response thereto generate a primary return signal. Moreover, the at least one telemetry means is adapted to

transmit the primary return signal over the wireless interface. Thereby, an aggregated secondary return signal may be generated, which is based on two or more primary return signals. The signal formats may also be adapted to the relevant transmission media, which of course is desirable.

According to a preferred embodiment of this aspect of the invention, at least one first IMD includes a telemetry means, which is adapted to receive the secondary inquiry signal, and in response thereto, generate a primary return signal. The telemetry means is also adapted to transmit the primary return signal over the wireless interface. This embodiment is advantageous, since it allows a direct communication with the IMD.

According to a preferred embodiment of this aspect of the invention, at least one second IMD is associated with a repeater unit. This unit, in turn, includes a telemetry means, which is adapted to receive the secondary inquiry signal, and in response thereto, generate a primary return signal. The telemetry means is also adapted to transmit the primary return signal over the wireless interface. The embodiment is advantageous, since it does not imply a usage of the energy resources in the IMD per se.

According to a preferred embodiment of this aspect of the invention, at least one third IMD is associated with a device box. This box, in turn, includes a telemetry means, which is adapted to receive the secondary inquiry signal, and in response thereto, generate the primary return signal. The telemetry means is also adapted to transmit the primary return signal over the wireless interface. The embodiment is advantageous, since it will not consume the energy resources in the IMD nor in its repeater unit.

According to a preferred embodiments of the above-described aspects of the invention, the first IMD is connected to an

indicator, the repeater unit contains an indicator respective the device box includes an indicator. This indicator is adapted to produce a local indication signal (e.g. optical and/or acoustic) in connection with the generation of the primary return signal. These embodiments are advantageous, since they all facilitate the physical location of a relevant device.

According to yet another aspect of the invention these objects are achieved by a local administration unit for communicating administrative signals pertaining to organization of not yet implanted IMDs of which each is associated with a respective telemetry means. The local administration unit contains at least one network interface and a wireless interface. The at least one network interface is adapted to receive at least one first inquiry signal from a remote external unit and transmit a second return signal to the remote external unit. The wireless interface is adapted to establish the existence of at least one implantable medical device by means of a transmitted second inquiry signal based on the first inquiry signal and at least one received first return signal, which is produced by at least one telemetry means in response to the second inquiry signal. Furthermore, the local administration unit is adapted to match registered device identities against information contained in the first and second inquiry signals, and produce, based on the result of the matching, the second return signal to form a basis for a course of action to be taken in respect of at least one implantable medical device.

The proposed local administration unit is advantageous, since it represents a link, which enables administration of distributed un-implanted IMDs from a central point. Although the proposed solution is primarily intended for cardiac devices, such as pace-makers and defibrillators, the invention is equally well applicable to any alternative type of IMDs, for example drug pumps or neurostimulators.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention is now to be explained more closely by means of preferred embodiments, which are disclosed as examples, and with reference to the attached drawings.

Figure 1 shows a prior-art system for remote communication with an IMD,

Figure 2 shows a system for organizing not yet implanted IMDs according to an embodiment of the invention,

Figure 3 illustrates, by means of a flow diagram, a method of performing a recall procedure of not yet implanted IMDs according to an embodiment of the invention,

Figure 4 shows a not yet implanted IMD connected to an indicator unit according to a first alternative embodiment of the invention,

Figure 5 shows a not yet implanted IMD associated with a repeater unit having an indicator according to a second alternative embodiment of the invention,

Figure 6 shows a not yet implanted IMD associated with a repeater unit having an indicator according to a third alternative embodiment of the invention, and

Figure 7 illustrates, by means of a flow diagram, a method of organizing not yet implanted IMDs according to an embodiment of the invention.

DESCRIPTION OF PREFERRED EMBODIMENTS OF THE INVENTION

Figure 2 shows a system for organizing not yet implanted IMDs 210a, 210b and 210c respectively according to an embodiment of the invention. Each of the IMDs 210a, 210b and 210c are

associated with a respective telemetry means for wireless data communication. A local administration unit 237 is positioned within the communication ranges of the IMDs' 210a, 210b and 210c telemetry means, i.e. relatively proximate to the devices. The local administration unit 237 may thus communicate with the IMDs 210a, 210b and 210c over a wireless interface 220a, 220b and 220c to their respective telemetry means. Preferably, the IMDs 210a, 210b and 210c are gathered in a storage area S at, for example a manufacturer M, a hospital H or a retailer. Depending on various conditions (such as type, model, version, buyer preferences etc.) the devices 210a, 210b and 210c may be packaged differently. Here, a first device 210a is packaged in a first device box 235a together with an associated first repeater unit 230a, correspondingly a second device 210b is packaged in a second device box 235b together with an associated second repeater unit 230b while a third device 210c is packaged in a third device box 235c without an associated repeater unit.

The local administration unit 237 has a network interface 240a, towards a communications network 240, e.g. the Internet, a PSTN (Public Switched Telephone Network) or equivalent. Hence, the unit 237 may be identified in the network 240 by means of a unique identifier, such as an IP-address or a telephone number.

A first remote external unit 270 has a network interface 240c towards the communications network 240, either directly or via at least one other network. In analogy to the local administration unit 237, the first remote external unit 270 has a unique identifier through which it may be addressed by other units having access to the network 240. Consequently, a connection may be established between the first remote external unit 270 and the local administration unit 237 over the network 240. Due to the wireless interface 220a, 220b and 220c, communication can also be accomplished between the first remote external unit 270 and the respective telemetry means associated with the IMDs 210a, 210b and 210c. Particularly, the first remote external unit 270 may generate a primary inquiry signal IQ', which is passed on to the

local administration unit 237. This unit 237 then converts the primary inquiry signal IQ' into a at least one secondary inquiry signal IQ'', which is adapted to the signal format of the wireless interface 220a, 220b and 220c. The secondary inquiry signal IQ'' is broadcast over the wireless interface 220a, 220b and 220c for intended reception at the IMDs 210a, 210b and 210c.

According to a preferred embodiment of the invention, the telemetry means associated with the IMDs 210a, 210b and 210c generate a respective primary return signal R' in response to the secondary inquiry signal IQ'', at least for those devices that fulfill a requirement specified in the secondary inquiry signal. This requirement may, for instance, imply matching the device's identity with the contents of a recall message. Alternatively, the requirement may relate to a stock inquiry or a billing operation. In addition to one or more device identities, the recall message may include information pertaining to advisory actions, notifications and upgrading. According to another preferred embodiment of the invention, any telemetry means receiving the secondary inquiry signal IQ'' shall reply with a respective primary return signal R', irrespective of whether the secondary inquiry signal IQ'' pertains to the corresponding implantable device or not.

In any case, one or more primary return signals R' may be sent via the wireless interface to the local administration unit 237 in response to the secondary inquiry signal IQ''. Preferably, the local administration unit 237 aggregates any received primary return signals R' into a joint message, which is sent in the form of a secondary return signal R'' to the first remote external unit 270 over the communications network 240. However, each received primary return signal R' may equally well be transformed into a particular secondary return signal R'', which are forwarded separately to the first remote external unit 270. Based on the at least one secondary return signal R'', the first remote external unit 270 determines a further course of action, such as generating an invoice (in the billing-case) or producing a return instruction (in the recall-case).

According to a preferred embodiment of the invention, the first remote external unit 270 has access to a first central data store 275, which contains device data D_d pertaining to at least one of the IMDs 210a, 210b and 210c. The first remote external unit 270 may thus retrieve device data D_d from the first central data store 275 and generate the primary inquiry signal IQ' based on this data D_d. Typically, the device data D_d includes the following information for each IMD: a device identity (e.g. a serial number), a batch number, a model designation, a version designation, a date of production and a latest registered location of the device.

According to a preferred embodiment of the invention, the primary inquiry signal IQ' is generated on basis of patient data D_p, i.e. information pertaining to patient specific parameters, such as previous medical condition, age, etc. The patient data D_p may either be entered on a completely manual basis or at least partially be retrieved from a second central data store 255 and be fed into a second remote external unit 250. Analogous to the first remote external unit 270, the second remote external unit 250 has a network interface 240b towards the communications network 240, either directly or via at least one other network. In most cases, the patient data D_p is entered via a particular hospital or clinic. Moreover, the patient data D_p is relevant to a physician practicing at this medical unit when deciding to implant a certain IMD. Therefore, the second remote external unit 250 and the second central data store 255 are preferably both located in a hospital area H. For instance, in an emergency situation, the physician may consult the second central data store 255 to obtain a recommendation of a suitable device for his/her patient. Given the patient data D_p, the second remote external unit 250 sends out a primary inquiry signal IQ' to at least one local administration unit 237 in proximity of a stock of IMDs being relatively readily accessible to the physician. Based on a corresponding secondary return signal R", the second remote external unit 250 recommends a suitable IMD in stock (provided, of course, that such device exists). Either the primary inquiry

signal IQ' is exclusively based on the patient data D_p or this signal IQ' also contains device data D_d from the first central data store 275.

Preferably, the necessary data is exchanged between the first remote external unit 270 and the second remote external unit 250 via the communications network 240. However, a direct connection for this purpose may also be set up between the units 250 and 270. For instance, data D_r pertaining to a recall instruction may be sent via such connection from the first remote external unit 270 to the second remote external unit 250.

Figure 3 illustrates, by means of a flow diagram, a method of performing a recall procedure with respect to one or more not yet implanted IMDs according to an embodiment of the invention. A first step 310 presumes that the manufacturer has become aware of an imperfection in, say a batch of IMDs. Expiry of a latest recommended implantation date represents a typical example of such imperfection. Namely, due to the chemical constituents of the batteries in an IMD, the device should be implanted before the chemical aging process has reached a certain stage in order to guarantee a stated life time for the device. The concerned devices are thus identified as candidates for a recall. In most cases when a recall proves necessary, this only affects those devices that have not yet been implanted into a patient. Due to the extremely rigorous safety regulations governing the IMD industry, the imperfections of a device that may be found after delivery are very seldom severe enough to justify explantation, i.e. be prone to cause immediate health risks for the patient. Typically, a follow-up examination is instead held earlier than originally planned in order to compensate for the imperfection. Today, a lower than expected battery capacity is one of the most common defects that are encountered after delivery of a device. This problem is rarely a ground for performing an immediate explantation of the device.

However if possible, implantation of a not yet implanted imper-

fect device should certainly be avoided. To this aim, a relevant recall message is sent out in a step 320. As mentioned above, the recall message may be included in a primary inquiry signal IQ' and a secondary inquiry signal IQ'' sent out from the remote external units 250 and/or 270 and the local administration unit 237 respectively.

A subsequent step 330, investigates whether a return signal has been received (i.e. a secondary return signal R'' has been received in either or both of the units 250 and 270) within a predetermined time limit, and if so, the procedure continues to a step 340. Otherwise, a step 350 investigates whether the recall message has been sent out a predetermined number of times n (where n is an integer ≥ 1). If the question posed in the step 350 is answered in the negative, the procedure loops back to the step 320 again. Otherwise, a step 360 is entered, which involves a manual recall operation. I.e. the proposed procedure has here failed to reach the relevant devices, possibly because all of them have already been implanted into patients.

In the step 340 however, an automatic recall procedure is initiated. This may involve transmitting a disable message or an instruction to a responsible clinician, which requests him/her to discard the concerned device(s) respective return it(them) to the manufacturer. Nevertheless, also this procedure normally includes various manual steps and measures before the recall is entirely completed.

Figure 4 shows a not yet implanted IMD 410, which is connected to an indicator unit 420 according to a first alternative embodiment of the invention. The IMD 410 contains a telemetry means C for exchange of data $D_R(IQ'', R')$ with external units via a wireless interface. The IMD 410 may thus receive a secondary inquiry signal IQ'' and transmit a primary return signal R'. Preferably, a sterile packing (not shown) surrounds both the device 410 and the indicator unit 420.

An indicator I in the indicator unit 420 is adapted to produce a local indication signal i_O, i_A in connection with the generation of the primary return signal R', such that the process of physically locating the device is facilitated. Preferably, the local indication signal is either an optical signal i_O, (e.g. produced by a light emitting diode, LED), an acoustic signal i_A (produced by a buzzer or similar) or a combination thereof. According to a preferred embodiment of the invention, the indicator unit 420 is connected to the IMD 410 via a cable to an electrode connector in the device 410.

Figure 5 shows a not yet implanted IMD 510, which is associated with a repeater unit 530 having an indicator I according to a second alternative embodiment of the invention in order to facilitate location of the device. Preferably, a sterile packing 512 surrounds at least the device 510. The IMD 510 and the repeater unit 530 are placed in a common device box 535. The repeater unit 530 is here equipped with a telemetry means C for exchange of data D_R(IQ'', R') with external units via a wireless interface. The IMD 510 may thus receive a secondary inquiry signal IQ'' and transmit a primary return signal R' via the repeater unit 530. By positioning the telemetry means C outside the device 510, the energy resources therein are economized.

The indicator I is adapted to produce a local indication signal i_O, i_A in connection with the generation of the primary return signal R', either in the form of an optical signal i_O, (e.g. produced by a light emitting diode, LED), an acoustic signal i_A (produced by a buzzer or similar) or a combination thereof.

Figure 6 shows a not yet implanted IMD 610, which in similarity with the device 510 above, is associated with a repeater unit 630 together with which it is placed in a device box 635. A sterile packing 612 surrounds the device 610, however not necessarily the repeater unit 630. Here, however, the box 635 itself includes a telemetry means C for exchange of data D_R(IQ'', R') with external units via a wireless interface. The IMD 610 may

thus receive a secondary inquiry signal IQ'' and transmit a primary return signal R' via the device box 635. Naturally, by positioning the telemetry means C outside both the device 610 and the repeater unit 635, the energy resources in both these units are economized.

The device box 635 also includes an indicator I, which is adapted to produce a local indication signal i_O, i_A in connection with the generation of the primary return signal R', either in the form of an optical signal i_O, (e.g. produced by a light emitting diode, LED), an acoustic signal i_A (produced by a buzzer or similar) or a combination thereof.

In order to sum up, the general method of organizing not yet implanted IMDs according to the invention will now be described with reference to figure 7.

A first step 710 involves generating a primary inquiry signal IQ' in an originating remote external unit. Then, a secondary inquiry signal IQ'' is broadcast in a step 720 over a wireless interface to a multitude of not yet implanted IMDs. Subsequently, a step 730 receives the secondary inquiry signal IQ'' and a following step 740 generates a primary return signal R' in response thereto. The primary return signal R' is generated in at least one telemetry means that is associated with the IMDs. After that, a step 750 transmits the at least one primary return signal R' over the wireless interface. Finally, a step 760 forwards a secondary return signal R'', based on the primary return signal R', to the originating remote external unit.

All of the process steps, as well as any sub-sequence of steps, described with reference to the figure 7 above may be controlled by means of a computer program being directly loadable into the internal memory of a computer, which includes appropriate software for controlling the necessary steps when the program is run on a computer. Furthermore, such computer programs can be recorded onto arbitrary kind of computer readable medium as

well as be transmitted over arbitrary type of network and transmission medium.

The term "comprises/comprising" when used in this specification is taken to specify the presence of stated features, integers, steps or components. However, the term does not preclude the presence or addition of one or more additional features, integers, steps or components or groups thereof.

The invention is not restricted to the described embodiments in the figures, but may be varied freely within the scope of the claims.

Claims

1. A method of organizing not yet implanted implantable medical devices, each implantable medical device (210a-c; 410, 510, 610) being associated with a respective telemetry means (C) for wireless exchange of data (D_R(IQ'',R')) with a remote external unit (250, 270), wherein the method involves:

communicating at least one inquiry signal (IQ'') and at least one return signal (R') over a wireless interface (220a-c) between at least one telemetry means (C) and a local administration unit (237),

establishing the existence of at least one implantable medical device,

matching registered device identities against information contained in an inquiry signal (IQ', IQ''), and

determining a course of action to be taken in respect of at least one implantable medical device based on the result of said matching.

2. A method according to claim 1, **characterized by**:

generating a primary inquiry signal (IQ') in the remote external unit (250, 270),

broadcasting, over a wireless interface (220a-c), a secondary inquiry signal (IQ'') being based on the primary inquiry signal (IQ'),

receiving, via the wireless interface (220a-c), the secondary inquiry signal (IQ'') in at least one telemetry means (C),

generating, in response to the secondary inquiry signal (IQ''), a respective primary return signal (R') in each of the at least one telemetry means (C) which are associated with an implemented medical device (210a-c; 410, 510, 610) fulfilling a requirement specified in the secondary inquiry signal (IQ''),

transmitting, via the wireless interface (220a-c), the at least one primary return signal (R') from the at least one telemetry means (C), and

forwarding, to the remote external unit (250, 270), a secondary return signal (R'') being based on the at least one primary return signal (R').

3. A method according to claim 2, **characterized by**
retrieving device data (D_d) pertaining to at least one implantable medical device (210a-c; 410, 510, 610) from a first central data store (275), and
generating the primary inquiry signal (IQ') on basis of the device data (D_d).

4. A method according to any one of the claims 2 or 3, **characterized by**
entering patient data (D_p) indicating at least one patient specific parameter with respect to a potential user of an implantable medical device (210a-c; 410, 510, 610), and
generating the primary inquiry signal (IQ') on further basis of the patient data (D_p).

5. A method according to claim 4, **characterized by** retrieving the patient data (D_p) from a second central data store (255).

6. A method according to claim 2, **characterized by** the primary inquiry signal (IQ') representing a step in a recall operation with respect to at least one implantable medical device (210a-c; 410, 510, 610).

7. A method according to claim 2, **characterized by** the primary inquiry signal (IQ') representing a step in a billing operation with respect to at least one implantable medical device (210a-c; 410, 510, 610).

8. A computer program directly loadable into the internal memory of a digital computer, comprising software for performing the steps of any of the claims 1 – 7 when said program is run on a computer.

9. A computer readable medium, having a program recorded thereon, where the program is to make a computer perform the

steps of any of the claims 1 – 7.

10. A system for organizing not yet implanted implantable medical devices, where each implantable medical device is associated with a respective telemetry means (C) for wireless exchange of data (D_R(IQ'',R')) with a remote external unit (250, 270), the system comprising:

a local administration unit (237) adapted to

communicate at least one inquiry signal (IQ'') and at least one return signal (R') with at least one telemetry means (C) over a wireless interface (220a-c),

establish the existence of at least one implantable medical device, and

match registered device identities against information contained in an inquiry signal (IQ', IQ''), and

at least one remote external unit (250; 270) having a network connection (240, 240a, 240b; 240c) to the local administration unit (237) and being adapted to determine a course of action to be taken in respect of at least one implantable medical device based on the result of a matching performed by the local administration unit (237).

11. A system according to claim 10, **characterized in that** it comprises:

a first central data store (275) containing device data (D_d) pertaining to at least one implantable medical device (210a-c; 410, 510, 610),

a first remote external unit (270) adapted to

retrieve device data (D_d) from the first central data store (275) and on basis thereof generate a primary inquiry signal (IQ'), and

receive and process a secondary return signal (R''),

a local administration unit (237) adapted to

receive the primary inquiry signal (IQ') and on basis thereof generate a secondary inquiry signal (IQ''),

broadcast the secondary inquiry signal (IQ'') over a

wireless interface (220a-c), and

receive at least one primary return signal (R') over the wireless interface (220a-c), and

at least one telemetry means (C) adapted to

receive the secondary inquiry signal (IQ'') via the wireless interface (220a-c) and in response thereto,

generate a primary return signal (R') and transmit this signal over the wireless interface (220a-c).

12. A system according to claim 11, **characterized in that** at least one first implantable medical device (410) comprises a telemetry means (C) adapted to receive the secondary inquiry signal (IQ''), and in response thereto, generate a primary return signal (R') and transmit this signal over the wireless interface (220c).

13. A system according to claim 12, **characterized in that** the at least one first implantable medical device (410) is connected to an indicator unit (420) including an indicator (I) adapted to produce a local indication signal (i_O, i_A) in connection with the generation of the primary return signal (R').

14. A system according to any one of the claims 10 - 13, **characterized in that** at least one second implantable medical device (510) is associated with a repeater unit (530), the repeater unit (530) comprising a telemetry means (C) adapted to receive the secondary inquiry signal (IQ''), and in response thereto, generate a primary return signal (R') and transmit this signal over the wireless interface (220a, b).

15. A system according to claim 14, **characterized in that** the repeater unit (530) comprises an indicator (I) adapted to produce a local indication signal (i_O, i_A) in connection with the generation of the primary return signal (R').

16. A system according to any one of the claims 10 - 15,

characterized in that at least one third implantable medical device (610) is associated with a device box (635), the device box (635) comprising a telemetry means (C) adapted to receive the secondary inquiry signal (IQ''), and in response thereto, generate a primary return signal (R') and transmit this signal over the wireless interface (220a, b).

17. A system according to claim 16, **characterized in that** the device box (635) comprises an indicator (I) adapted to produce a local indication signal (i_O, i_A) in connection with the generation of the primary return signal (R').

18. A local administration unit (237) for communicating administrative signals pertaining to organization of not yet implanted implantable medical devices (210a-c) of which each is associated with a respective telemetry means (C), comprising

at least one network interface (240a) adapted to receive at least one first inquiry signal (IQ') from a remote external unit (250; 270), and transmit a second return signal (R'') to the remote external unit (250; 270), and

a wireless interface (220a-c) adapted to establish the existence of at least one implantable medical device by means of a transmitted second inquiry signal (IQ'') based on the first inquiry signal (IQ') and at least one received first return signal (R') produced by at least one telemetry means (C) in response to the second inquiry signal (IQ''),

the unit (237) being adapted to:

match registered device identities against information contained in the first and second inquiry signals (IQ'; IQ''), and

produce, based on the result of the matching, the second return signal (R'') to form a basis for a course of action to be taken in respect of at least one implantable medical device.

19. A local administration unit (237) according to claim 18, **characterized in that**

the at least one network interface (240a) is adapted to:

receive a primary inquiry signal (IQ') from a remote external unit (250, 270) and forward the primary inquiry signal (IQ') for generation of a secondary inquiry signal (IQ''), and

transmit a secondary return signal (R'') to the remote external unit (250, 270), and

the wireless interface (220a-c) is adapted to

broadcast the secondary inquiry signal (IQ'') to the telemetry means (C) of a plurality of not yet implanted implantable medical devices (210a-c), and

receive at least one primary return signal (R') over the wireless interface (220a-c) and forward the at least one primary return signal (R') for generation of the secondary return signal (R''), the at least one primary return signal (R') being produced by the telemetry means (C) in response to the secondary inquiry signal (IQ'').

20. A local administration unit (237) according to claim 19, **characterized in that** the at least one network interface (240a) is adapted to communicate the primary inquiry signal (IQ') and the secondary return signal (R'') via at least one communications network (240).

Fig 1

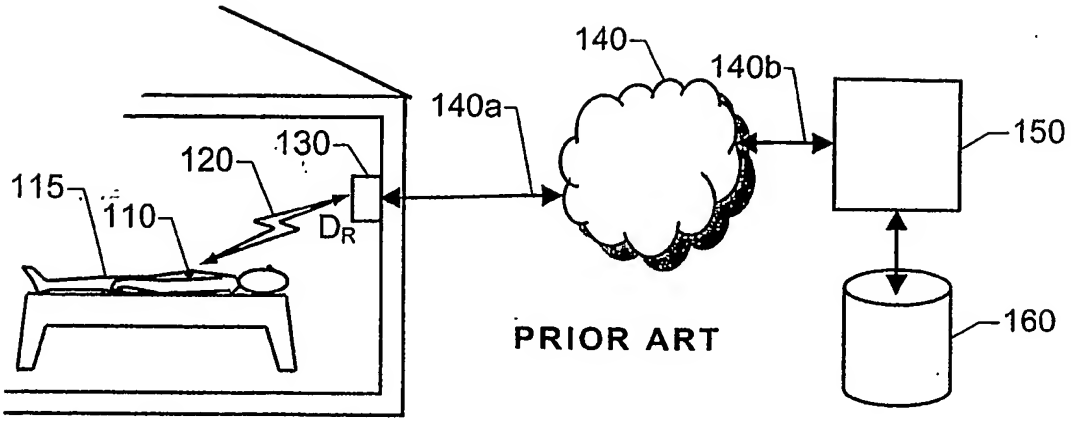


Fig 2

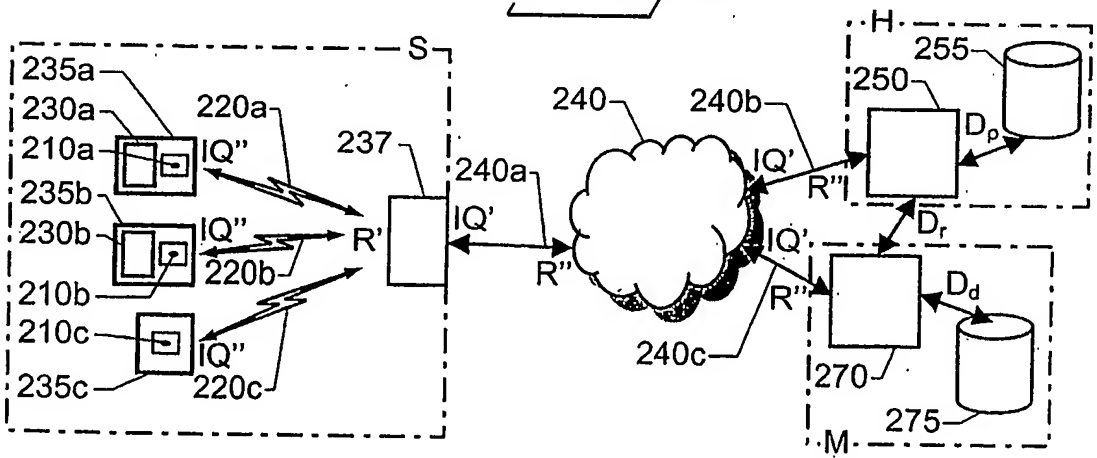


Fig 4

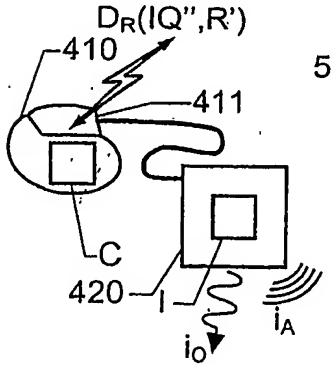


Fig 5

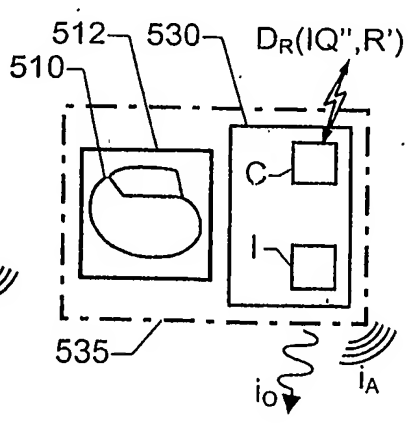


Fig 6

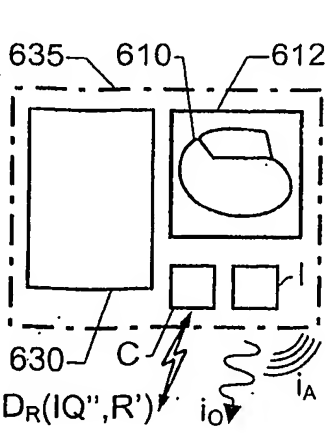


Fig 3

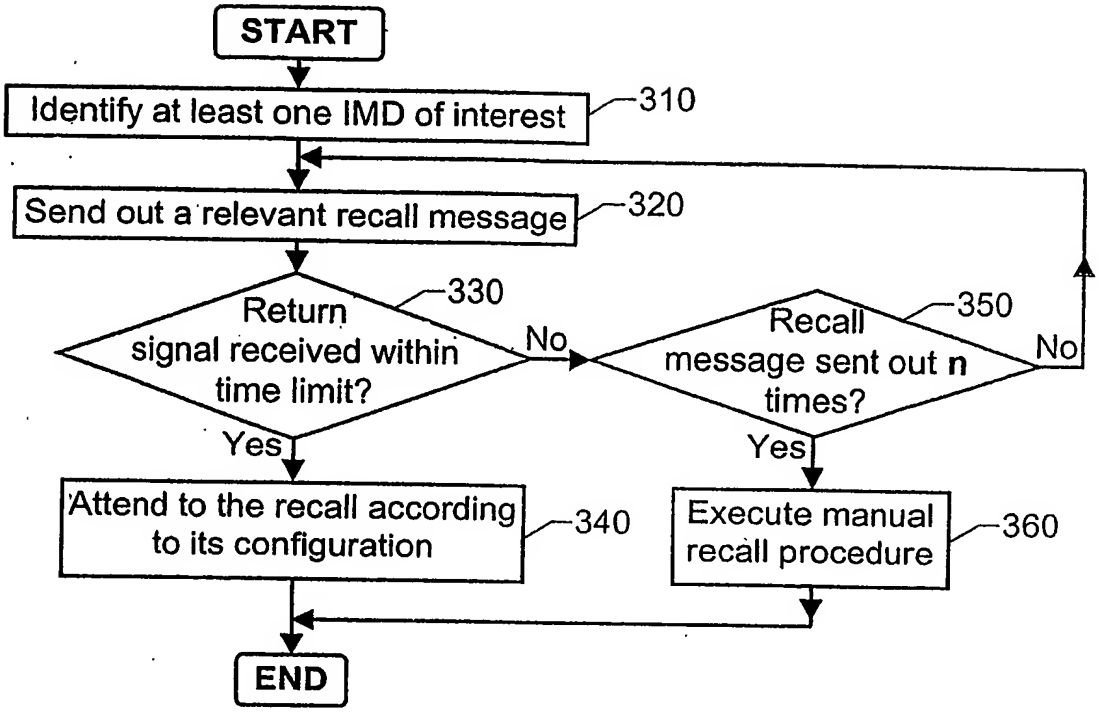
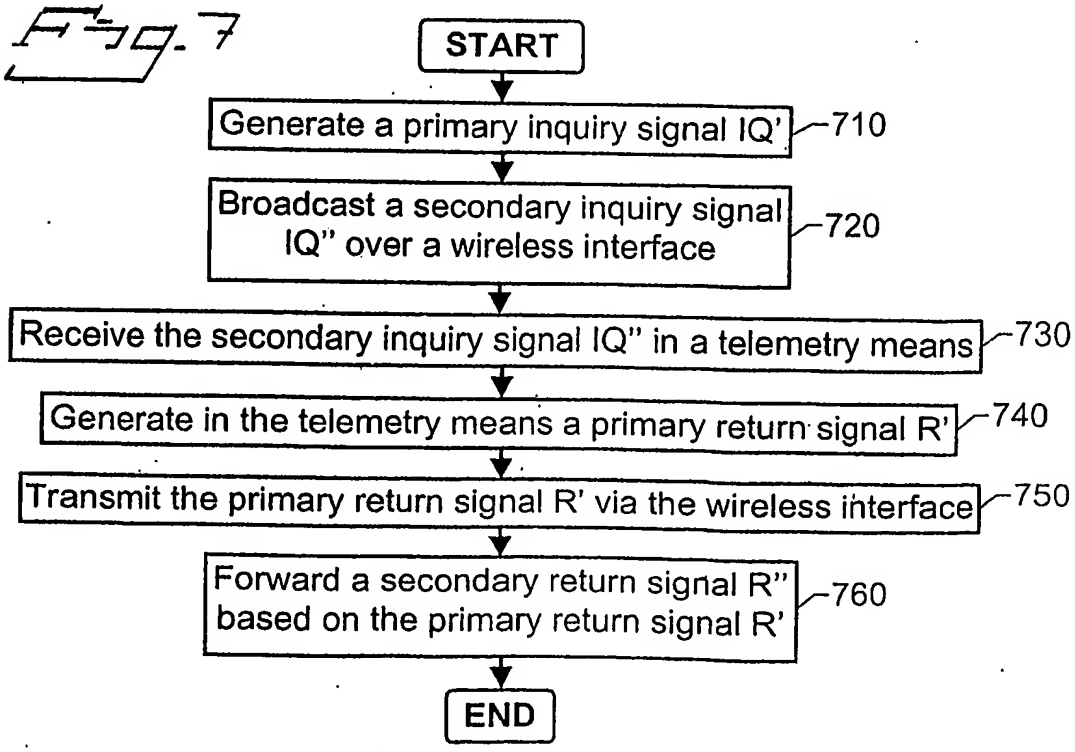

START
Identify at least one IMD of interest
310
Send out a relevant recall message
320
Return signal received within time limit?
330
No
Yes
Recall message sent out n times?
350
No
Yes
Attend to the recall according to its configuration
340
Execute manual recall procedure
360
END

Fig 7


START
Generate a primary inquiry signal IQ'
710
Broadcast a secondary inquiry signal IQ" over a wireless interface
720
Receive the secondary inquiry signal IQ" in a telemetry means
730
Generate in the telemetry means a primary return signal R'
740
Transmit the primary return signal R' via the wireless interface
750
Forward a secondary return signal R" based on the primary return signal R'
760
END

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/02182

A. CLASSIFICATION OF SUBJECT MATTER

IPC7: A61N 1/02, G06F 19/00
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC7: A61N, G06F, A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EPO-INTERNAL, WPI DATA, PAJ, MEDLINE, INSPEC, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0182210 A2 (MEDTRONIC, INC.), 1 November 2001 (01.11.01), see page 9, lines 4-22 and abstract --	1-20
A	US 6083248 A (DAVID L. THOMPSON), 4 July 2000 (04.07.00), see column 5, lines 10-38, figure 3, abstract --	1-20
A	US 6249705 B1 (JEFFERY D. SNELL), 19 June 2001 (19.06.01), see abstract --	1-20
A	EP 1062981 A2 (BIOTRONIK), 27 December 2000 (27.12.00), see abstract --	1-20

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
7 February 2003	12 -02- 2003
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Sofie Carlsson/EÖ Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 02/02182

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 0149368 A1 (MEDTRONIC, INC.), 12 July 2001 (12.07.01), see abstract -- ---	1-20

INTERNATIONAL SEARCH REPORT

Information on patent family members

30/12/02

International application No.
PCT/SE 02/02182

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		US 2002032720 A	14/03/02
US 6083248 A	04/07/00	EP 1133255 A	19/09/01
		WO 0030529 A	02/06/00
		US 6292698 B	18/09/01
		AU 709767 B	09/09/99
		AU 6176996 A	22/01/97
		CA 2224520 A	09/01/97
		EP 0939662 A	08/09/99
		JP 11508165 T	21/07/99
		US 5752976 A	19/05/98
		WO 9700708 A	09/01/97
US 6249705 B1	19/06/01	NONE	
EP 1062981 A2	27/12/00	DE 19930241 A	28/12/00
		US 6470215 B	22/10/02
WO 0149368 A1	12/07/01	EP 1246666 A	09/10/02